

**THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA**

REBECCA COWEN,)	
)	
Plaintiff,)	
)	Case No. 22-cv-00157-CVE-JFJ
v.)	
)	Judge Terrance Kern
WALGREEN CO, an Illinois corporation,)	
d/b/a, WALGREENS DRUGSTORE NO.)	
15751,)	
)	
Defendant.)	

**MOTION TO DISMISS AND BRIEF IN SUPPORT
OF DEFENDANT WALGREEN CO**

COMES NOW Defendant, Walgreen Co. (“Defendant” or “Walgreens”),¹ specially appearing by and through its counsel of record, the law firm of HOLDEN LITIGATION, and respectfully submits its Motion to Dismiss and brief in Support pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Walgreens respectfully requests the Court enter an order dismissing all claims brought against it in the underlying Petition by Plaintiff Rebecca Cowen (“Plaintiff”). As set forth below, Plaintiff’s tort claims are barred by the Public Readiness and Emergency Preparedness Act provisions (“PREP Act”), found at 42 U.S.C.A. §§ 247d-6d and 247d-6e.

I. INTRODUCTION

Plaintiff alleges, on September 20, 2021, she sought a flu vaccination from a Walgreens store in Bartlesville, Oklahoma. However, Plaintiff alleges, instead, a Walgreens employee administered a Moderna COVID-19 vaccination to Plaintiff without her knowledge or consent.

¹ The entities named by Plaintiff are either nonexistent or improperly named. The correct entity for this suit is Walgreen Co.

Plaintiff's Petition asserts state law claims for negligence and vicarious liability against Walgreens. Plaintiff seeks actual damages exceeding \$75,000, along with punitive damages.

Plaintiff's claims are barred as a matter of law by the immunity provided to Walgreens under the PREP Act. The Act immunizes entities providing countermeasures to the COVID-19 pandemic. The distribution and administration of the Moderna COVID-19 vaccine is defined as a protected countermeasure. The PREP Act preempts all state law causes of action against covered entities, with the sole exception to immunity being a federal cause of action for death or serious physical injury proximately caused by willful misconduct of the defendant. Plaintiff alleges neither death, serious physical injury, nor willful misconduct by Walgreens. Accordingly, Walgreens is entitled to dismissal of Plaintiff's claims against it.

II. BACKGROUND AND PROCEDURAL POSTURE²

On January 31, 2020, the United States Secretary of Health and Human Services ("HHS Secretary") declared that as of January 27, 2020, a public health emergency existed because of COVID-19.³ That declaration has remained in effect through the present.⁴

On March 17, 2020, the HHS Secretary issued a declaration under the PREP Act "to provide liability immunity for activities related to medical countermeasures against COVID-19." *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 15198, 15199. The Declaration provides immunity for covered persons for the administration of covered countermeasures, including

² Walgreens assumes the facts in Plaintiff's Petition as true for the purpose of this Motion only.

³ See *Determination that a Public Health Emergency Exists*, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (retrieved August 3, 2022).

⁴ See *Renewal of Determination that a Public Health Emergency Exists*, <https://aspr.hhs.gov/legal/PHE/Pages/covid19-15jul2022.aspx> (retrieved August 3, 2022).

“any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . .” *Id.* at 15202.

Under the HHS Secretary’s Declaration, covered persons include “qualified persons” who are “authorized to prescribe, dispense, and administer COVID-19 vaccines. . .” *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872, 7873. That includes State-licensed pharmacists, supervised pharmacy interns, and qualified pharmacy technicians. *Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 41977, 41978. (The original declaration and its subsequent amendments hereinafter collectively referred to as the “Declaration”). Additionally, based upon the authority granted to it under the HHS Secretary’s Declaration, on October 29, 2020, the Office of the Assistant Secretary for Health clarified that “pharmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B) when their staff pharmacists order and administer . . . covered countermeasures consistent with the terms and conditions of the Secretary’s Declaration and guidance, as of the date that these staff pharmacists . . . were authorized to order or administer these covered countermeasures.” (Ex. D - *PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures*, p. 2).

On September 20, 2021, Plaintiff scheduled a same-day, online appointment to obtain a flu vaccination at Walgreen Drugstore #15751 in Bartlesville, Oklahoma. (Ex. B – Petition, ¶¶ 9-10). Upon arrival at Walgreens, Plaintiff was taken to a private area to receive the flu vaccination. (*Id.* at ¶ 10). According to Plaintiff, a Walgreens employee subsequently injected her with the Moderna COVID-19 vaccine without first confirming what injection Plaintiff was

there to receive. (*Id.* at ¶¶ 11-12). Shortly thereafter, Plaintiff was given a vaccination card by the Walgreens employee noting the Moderna vaccine injection date, which was the first time Plaintiff became aware that she was given the incorrect vaccination. (*Id.* at ¶ 13).

This action was originally filed in the District Court of Washington County, Oklahoma as Case No. CJ-2022-49 on March 10, 2022. (Ex. A – Summons; Ex. B - Petition). Plaintiff’s Petition asserts causes of action for, inter alia, negligence and vicarious liability.⁵ (Ex. B, ¶¶ 15-20). Plaintiff seeks to recover actual and compensatory damages exceeding \$75,000.00, along with punitive damages. (*Id.* at p. 4). However, Plaintiff’s Petition alleges no facts indicating that injection of the Moderna COVID-19 vaccine proximately caused her death or physical injury, serious or otherwise. (*See generally*, Ex. B, ¶¶ 7-22). Plaintiff’s Petition also alleges no facts indicating that Walgreens committed willful misconduct. (*Id.*).

The matter was removed to this Court on April 6, 2022. (Notice of Removal, Dkt. No. 2). This case is removable under 28 U.S.C.A. § 1441(a) on the basis of original jurisdiction because Plaintiff’s Petition asserts a claim arising under and governed by federal law within the meaning of § 1331. Specifically, the PREP Act, 42 U.S.C.A. §§ 247d-6d(d), 247d-6e. (Notice of Removal, Dkt. No. 2, pp. 2-3).^{6 7}

⁵ Plaintiff also alleges Defendant “did not maintain proper policies and procedures concerning the patients concerns in regards [to] obtaining the COVID-19 shot.” (Ex. B, ¶ 22).

⁶ Walgreens notes that, although not asserted in the Notice of Removal, this Court also has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332, which provides for original jurisdiction over lawsuits where there is complete diversity of citizenship between the parties, and the amount in controversy, exclusive of interest and costs, exceeds \$75,000. See 28 U.S.C. § 1332(a); *Johnson v. Rodrigues*, 226 F.3d 1103, 1107 (10th Cir. 2000); *Symes v. Harris*, 472 F.3d 754 (10th Cir. 2006). Here, Plaintiff was and is a citizen of Oklahoma. Walgreens is a foreign corporation, organized and existing under the laws of the State of Illinois, with its principal place of business in the State of Illinois. Plaintiff also seeks to recover damages in excess of \$75,000.

⁷ Removal is also proper because this Court has Subject Matter Jurisdiction under the Federal Officer statute, 28 U.S.C. § 1442(a)(1).

III. ARGUMENT AND AUTHORITY

A. Legal Standard for a Motion to Dismiss

Plaintiff's Petition should be dismissed under Fed.R.Civ.P. 12(b)(6) for failure to state a claim upon which relief may be granted, and alternatively may be dismissed under Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction.

i. *Rule 12(b)(6) – Failure to State a Claim*

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plausibility requires “more than a sheer possibility that a defendant has acted unlawfully” and more than labels, conclusions, “formulaic recitation of the elements,” or “naked assertions.” *Id.* Questions of statutory interpretation “are questions of law ripe for resolution at the pleadings stage.” *Simmons v. Galvin*, 575 F.3d 24, 30 (1st Cir. 2009). Further, “it is proper to dismiss a claim on the pleadings based on an affirmative defense. But that is only when the complaint itself admits all the elements of the affirmative defense by alleging the factual basis for those elements.” *Fernandez v. Clean House, LLC*, 883 F.3d 1296, 1299 (10th Cir. 2018). This includes where there is a challenge on qualified immunity grounds. *See, e.g., Truman v. Orem City*, 998 F.3d 1164, 1171 (10th Cir. 2021), *opinion withdrawn and superseded on reh'g in part on other grounds, Truman v. Orem City*, 1 F.4th 1227 (10th Cir. 2021). Dismissal under this standard is also appropriate where there is a failure to exhaust administrative remedies. *See, e.g., Jernigan v. Stuchell*, 304 F.3d 1030, 1032 (10th Cir. 2002). Finally, when deciding a motion to dismiss under Rule 12(b)(6), a court may consider matters of public record and facts susceptible to judicial notice. *See, Tal v. Hogan*, 453 F.3d 1244, 1265 at n. 24 (10th Cir. 2006). Whereas here, the elements of an

affirmative defense based on the PREP Act appear on the face of the Petition, dismissal at the pleading stage pursuant to Rule 12(b)(6) is appropriate. *Garcia v. Welltower OpCo Group LLC*, 2021 WL 492581, at *10 (C.D. Cal. Feb. 10, 2021) (citing *Jones v. Bock*, 549 U.S. 199, 215, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007)).

ii. Rule 12(b)(1) – Lack of Subject-Matter Jurisdiction

Generally, Rule 12(b)(1) motions to dismiss for lack of subject matter jurisdiction take two forms. First, a facial attack on the complaint's allegations as to subject matter jurisdiction questions the sufficiency of the complaint. In reviewing a facial attack on the complaint, a district court must accept the allegations in the complaint as true.

Second, a party may go beyond allegations contained in the complaint and challenge the facts upon which subject matter jurisdiction depends. When reviewing a factual attack on subject matter jurisdiction, a district court may not presume the truthfulness of the complaint's factual allegations. A court has wide discretion to allow affidavits, other documents, and a limited evidentiary hearing to resolve disputed jurisdictional facts under Rule 12(b)(1).

Holt v. United States, 46 F.3d 1000, 1002–03 (10th Cir. 1995) (citations omitted).

In this case, a factual attack is not essential; however, Walgreens can submit any additional facts necessary to resolve the question of immunity. “Plaintiff[‘s] state law claims . . . are preempted by the PREP Act and . . . the [Petition] must be dismissed for lack of subject matter jurisdiction.” *Parker v. St. Lawrence County Pub. Health Dept.*, 954 N.Y.S.2d 259, 263 (NY App. Div. 2012).

B. Walgreens is Immune from Suit Under the PREP Act and the HHS Secretary’s Declaration

The intent of the PREP Act was to remove liability concerns -- specifically for countermeasures and covered persons -- so that resources would remain available during an emergency. Otherwise, such critical resources would simply shut down rather than expose

themselves to endless lawsuits.⁸ The Act has a broad reach in its intended scope of protection and empowers the HHS Secretary to issue a written declaration identifying the “covered persons” who shall be immune from suit and liability under Federal and State law with respect to **all claims for loss caused by, arising out of, relating to, or resulting from** the administration or use of a “covered countermeasure” during a health emergency. 42 U.S.C. §§ 247d–6d(a)(1), (b) (emphasis added). PREP Act immunity applies to “any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution, . . . dispensing, prescribing, [or] administration, . . . or use of such countermeasure.” *Id.* at ¶ (a)(2)(B).

Further, on March 17, 2020, the HHS Secretary issued a declaration under the PREP Act “to provide liability immunity for activities related to medical countermeasures against COVID-19.” *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 15198, 15199. The Declaration provides immunity for covered persons for the administration of covered countermeasures, including “any antiviral, any other drug, any biologic, any diagnostic, any other device, or **any vaccine**, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . .” *Id.* at 15202 (emphasis added).

Together, these authorities provide immunity to an individual or entity under the PREP Act if (1) they are a “covered person,” (2) they are administering or using a “covered countermeasure,” (3) the claim against which immunity is asserted “arises out of, relates to, or

⁸ See P. Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 6, No 4, 2008.

results from” the administration or use of the subject countermeasure, (4) the administration or use occurs during “effective period,” PREP Act, 42 U.S.C. §§ 247d-6d, 247d-6e, Declaration, *supra*. Here, Walgreens meets all of these elements.

i. Walgreens and its Employee are Each a “Covered Person”

Plaintiff’s own allegations establish that Walgreens and its employees are “covered person[s],” as defined by 42 U.S.C.A. § 247d-6d. Under PREP Act section 42 U.S.C. § 247d-6d, a “[c]overed person” includes distributors of a covered countermeasure, **qualified person who prescribed, administered, or dispensed such countermeasure**, or their agents or employees. *Id.* at ¶ (i)(2)(B) (emphasis added). The HHS Secretary’s Declaration states that “Covered Countermeasures are any antiviral, any other drug, any biologic, **or any vaccine**, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom . . .” 85 FR 15198, 15202 (emphasis added).

In the present case, Walgreens and its employee meet the definition of covered person because they are “qualified persons” who “administered, or dispensed” a “covered countermeasure.” The term “qualified person” includes: (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary. 42 U.S.C. § 247d-6d(i)(8).

Under the HHS Secretary’s Declaration, “qualified persons” are those “authorized to prescribe, dispense, and administer COVID-19 vaccines . . .” *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872, 7873. That includes State-licensed pharmacists, supervised

pharmacy interns, and qualified pharmacy technicians. *Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 41977, 41978.

Further, the vaccine must be authorized, approved, or licensed by the FDA. *Id.* In the case of a COVID-19 vaccine, the vaccination must also be ordered and administered according to ACIP's COVID-19 vaccine recommendations. *Id.* “As used in the PREP Act Authorizations, the phrase, ‘must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s).’ means that the vaccine must be one that ACIP recommends for the prevention of COVID-19; it does not mean that the vaccine be administered pursuant to any particular allocation guidance or recommendation.” (Ex. E - Advisory Opinion 21-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration Under the Act January 12, 2021, p. 1).⁹ On December 19, 2020, the ACIP issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged 18 years or over for the prevention of COVID-19.¹⁰

In addition, on October 29, 2020, the Office of the Assistant Secretary of Health, as an Authority Having Jurisdiction under the HHS Secretary’s Declaration ¹¹ clarified that:

⁹ In the Fourth Amendment to the PREP Act, the HHS Secretary declared that the PREP Act “must be construed in accordance with the advisory opinions on the PREP Act issued by HHS's Office of the General Counsel (“OGC”), and that it “expressly incorporates the Advisory Opinions for that purpose.” *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1024 (D. Colo. 2021) (quoting Fourth Amendment, 85 Fed. Reg. 79190).

¹⁰ See *The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020* <https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm> (retrieved August 5, 2022).

¹¹ See 85 FR 15198, 15200

The Secretary may specify that liability immunity is in effect only to Covered
(continued on next page)

pharmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B) when their staff pharmacists order and administer . . . these covered countermeasures consistent with the terms and conditions of the Secretary’s Declaration and guidance, as of the date that these staff pharmacists . . . were authorized to order or administer these covered countermeasures. **Such pharmacies qualify as “covered persons” under the PREP Act**, subject to other applicable requirements of the PREP Act and the Declaration. **Such pharmacies are therefore immune from suit and liability under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of “covered countermeasures” as described in the Secretary’s Declaration and guidance, including the administration or use of COVID-19 tests authorized, approved, or cleared by the FDA and the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines**

(Ex. D - PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, p. 2) (citations and footnotes omitted) (emphasis added).

In the case at bar, Walgreens, and the employee that allegedly injected Plaintiff with the Moderna COVID-19 vaccine are “qualified persons” under the PREP Act and the HHS Secretary’s Declaration. Specifically, “[o]n December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of [the] Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older” (Ex. C – June 17, 2022 FDA Letter of Authorization, p. 2). On the same day, the ACIP issued an interim recommendation for use of the Moderna COVID-19 vaccine

Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to . . . activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency.

Section VII defines the terms “Authority Having Jurisdiction” and “Declaration of an emergency.” We have specified in the definition that **Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.**

in persons aged 18 years or over for the prevention of COVID-19. (Ex. D, p. 2). Walgreens has dispensed and administered COVID-19 vaccines since December 2020. (Ex. F – Affidavit of Tabitha Gray, ¶ 5).

Further, on September 20, 2021 - the date of the alleged incident – Austin Crandall was the pharmacist on duty at Walgreen Drugstore #15751 in Bartlesville, Oklahoma, and the Walgreens employee that allegedly injected Plaintiff Rebecca Cowen with the Moderna COVID-19. (Ex. F, ¶ 7). On September 20, 2021, Austin Crandall maintained a license in good standing with the Oklahoma Board of Pharmacy and was qualified to administer vaccines in the State of Oklahoma. (Ex. F, ¶¶ 8-14).¹² Finally, it can be inferred from the allegations of Plaintiff’s Petition that she is at least 18 years of age,¹³ and thus eligible to receive the Moderna COVID-19 vaccine under both the FDA Emergency Use Authorization and the ACIP recommendations for the Moderna vaccine. Under these circumstances, both Walgreens and

¹² See *Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19* 86 FR 41977, 41978.

The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

¹³ Specifically, Plaintiff filed suit in her own name. Therefore, it can be inferred that she is not a minor that lacks the capacity to sue. See Fed Rules Civ Proc R 17(b)(1) (“Capacity to sue or be sued is determined . . . for an individual who is not acting in a representative capacity, by the law of the individual’s domicile.”). “Oklahoma’s statutory law specifically provides that minors may protect their rights by suing through their next friend.”). *Gens v. Casady Sch.*, 2008 OK 5, ¶ 14, 177 P.3d 565, 570–71. See also, 12 O.S. § 2017.

its employee, Austin Crandall are “qualified persons” as defined in the PREP Act and the HHS Secretary’s Declaration. Consequently, as qualified persons, Walgreens and Austin Crandall are each a “covered person” under the PREP Act and the HHS Secretary’s Declaration.

ii. Plaintiff’s Allegations Involve “Covered Countermeasures”

Plaintiffs’ allegations also establish that Walgreens and its employee, Austin Crandall, were engaged in the administration of “covered countermeasures” on the date of the incident. The PREP Act defines a “covered countermeasure” to include a “qualified pandemic or epidemic product.” 42 U.S.C. § 247d-6d (i)(1)(A). The term “qualified pandemic or epidemic product” means:

a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), 2 biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))
2 that is--

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

- (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
- (II) to limit the harm such pandemic or epidemic might otherwise cause;

Id. at ¶ (i)(7).

The HHS Secretary’s Declaration states that “Covered Countermeasures are any antiviral, any other drug, any biologic, **or any vaccine**, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom” 85 FR 15198, 15202 (emphasis added). “On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of [the] Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older” (Ex. C – June 17, 2022 FDA Letter of Authorization, p. 2).

Further, as stated above, under the HHS Secretary’s Declaration, “qualified persons” include those who are “authorized to prescribe, dispense, and administer COVID-19 vaccines” *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872, 7873. See also, *Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act April 17, 2020, as Modified on May 19, 2020*, p. 3. (“Any drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure.”).¹⁴

Administration of a Covered **Countermeasure means physical provision of the countermeasures to recipients**, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of “administration” extends only to physical provision of a countermeasure to a recipient, such as vaccination

85 FR 15198, 15200 (emphasis added).

In the present case, the allegations in Plaintiff’s Petition clearly establish that she was administered the Moderna COVID-19 vaccine. A “covered countermeasure” as defined by the PREP Act and the HHS Secretary’s Declaration.

¹⁴ <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (retrieved August 5, 2022).

iii. Plaintiff's Claims were "Caused By" "Ar[ose] Out of, Relate[d] To, or Resulted From" The Administration or Use of the Moderna COVID-19 Vaccine

As detailed above, the PREP Act covers **all claims for loss caused by, arising out of, relating to, or resulting from** the administration or use of a "covered countermeasure" during a health emergency. 42 U.S.C. § 247d–6d(a)(1), (b) (emphasis added). As established above, the Moderna COVID-19 allegedly administered to Plaintiff is a covered countermeasure. PREP Act immunity applies to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . dispensing, prescribing, [or] administration, . . . or use of such countermeasure." *Id.* at ¶ (a)(2)(B).

"Loss" "means any type of loss, including-- (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss."

Id. at ¶ (a)(2)(A)(i)-(iv).

Here, Plaintiff alleges she was injected with the Moderna COVID-19 vaccine by a Walgreens employee without Plaintiff's knowledge or consent. The only allegation regarding injury in Plaintiff's Petition is that she "was distraught over the negligent injection as she did NOT want the injection for her own personal reasons and communicated the same to the Walgreens employee." (Ex. B, ¶ 14) (emphasis original). Plaintiff's own allegations thus establish that her distress was caused by, arose out of, related to, or resulted from the administration of a covered countermeasure – i.e., administration of the Moderna COVID-19 vaccine by Walgreens' pharmacist, Austin Crandall.

The broad language of the PREP Act makes clear that it applies to “all” claims for loss, including those for mental or emotional injury, or fear of mental, or emotional injury. 42 U.S.C. §§ 247d–6d(a)(1)-(b), (a)(2)(A)(ii)-(iii). Further, other courts have previously found that PREP Act immunity applicable in cases involving injuries arising from vaccinations given without consent.

In *Kehler v. Hood*, 4:11CV1416 FRB, 2012 WL 1945952, (E.D. Mo. May 30, 2012),¹⁵ Plaintiff Larry Kehler filed a state-court action in Missouri “alleging that defendant Dr. Diane Hood and her employer, Internal Medicine of St. Luke's, LLC (St.Luke's), were negligent in their failure to obtain Mr. Kehler's informed consent prior to the administration of the H1N1 vaccination and in their failure to obtain a consult from a specialist prior to the administration of the vaccination.” *Id.* at *1. Thereafter, the defendants filed third-party indemnification and contribution claims against the H1N1 vaccine manufacturer, Novartis. *Id.* Novartis removed the matter to the Eastern District of Missouri pursuant to 28 U.S.C. § 1442(a)(1), the federal officer removal statute. *Id.*

Upon removal, Novartis moved for dismissal based upon PREP Act immunity. *Id.* In its analysis, the *Kehler* court agreed with the parties and found that “[Novartis] the alleged manufacturer of the H1N1 vaccine at issue here, is protected by the PREP Act and is absolutely immune from liability for any type of loss caused by the vaccine.” *Id.* at *3.¹⁶

¹⁵ Attached as Ex. G.

¹⁶ The *Kehler* court then remanded the case to state court against the doctor and hospital defendants, despite the defendants’ argument that claims against them were likewise barred by the PREP Act, and thus federal question jurisdiction existed. *Id.* at *3-4. The court reasoned that the mere assertion of a federal statute as a defense to a claim did not give rise to a federal question and suggested that plaintiffs’ state law claims of medical negligence were based on the conduct of defendants which occurred prior to the administration of the vaccine. *Id.* at *4.

Similarly, in *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 102 A.D.3d 140, 954 N.Y.S.2d 259 (2012);¹⁷

[o]n December 3, 2009, pursuant to the [HHS] Secretary's declarations [recommending the administration of the H1N1 influenza antiviral vaccination], defendant St. Lawrence County Public Health Department (hereinafter defendant) held a vaccination clinic at defendant Lisbon Central School in the Town of Lisbon, St. Lawrence County. Although **plaintiff did not execute a parental consent form authorizing the inoculation of her daughter, then a kindergartner, a nurse employed by defendant nonetheless administered a vaccination to the child.**

Id. at 141–42. The plaintiff in *Parker* subsequently filed an action in New York state court “alleging that the administration of the inoculation without consent constituted negligence and resulted in a battery upon her daughter.” *Id.* The defendant health department moved for dismissal based upon PREP Act immunity, which the trial court denied. *Id.*

On appeal, the *Parker* court reversed the trial court, holding that “the PREP Act preempt[ed] plaintiff's state law claims for negligence and battery . . .” *Id.* at 142. Relying on the broad language of the PREP Act, the *Parker* court concluded:

Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent (*see Bruesewitz v Wyeth LLC*, 562 US —, —, 131 S Ct 1068, 1088 [2011]).

Id. at 143–44. Supporting its conclusion, The *Parker* court noted Justice Sotomayor's dissent in *Bruesewitz* for its citation of the PREP Act as an exemplar of Congress' intent to categorically preempt certain liability claims. The dissent in *Bruesewitz* stated:

Indeed, when Congress intends to pre-empt design defect claims categorically, it does so using categorical (e.g., “all”) and/or declarative language (e.g., “shall”), rather than a conditional term (“if”). **For example, in a related**

¹⁷ Attached as Ex. H.

context, Congress has authorized the Secretary of Health and Human Services to designate a vaccine designed to prevent a pandemic or epidemic as a “covered countermeasure.” 42 U.S.C. §§ 247d–6d(b), (i)(1), (i)(7)(A)(i). With respect to such “covered countermeasure[s],” Congress provided that subject to certain exceptions, “a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure,” § 247d–6d(a)(1) (emphasis added), including specifically claims relating to “the design” of the countermeasure, § 247d–6d(a)(2)(B).

Bruesewitz v. Wyeth LLC, 562 U.S. 223, 253, 131 S. Ct. 1068, 1088, 179 L. Ed. 2d 1 (2011)

(emphasis added).

Importantly, the court in *Parker* further stated:

We are unpersuaded by plaintiff's assertion that immunity pursuant to the PREP Act does not extend to qualified persons who administer a covered countermeasure to an individual without consent. The immunity provisions of the PREP Act are triggered where, as here, the vaccines are purchased pursuant to a federal contract or agreement (see 75 Fed Reg 63656, 63658 [2010]) and, despite plaintiff's assertions to the contrary, Executive Order No. 29 Executive Order No. 29 neither defines nor otherwise places limitations upon the scope or applicability of such immunity. **Plaintiff also asserts that Congress could not have intended to immunize such “radical measures” as administering a vaccination without consent. It is not our role, however, to speculate upon congressional judgments. Rather, we must presume that Congress fully understood that errors in administering a vaccination program may have physical as well as emotional consequences, and determined that such potential tort liability must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency.**

Id. (emphasis added).

Here, analogous to both *Kehler* and *Parker*, Plaintiff alleges that she was administered a Moderna COVID-19 vaccine without her consent. Plaintiff further alleges she was injured as a result of the negligent injection. As stated supra, that vaccine injection was a covered countermeasure which was administered by a qualified person, Walgreens pharmacist, Austin Crandall. PREP Act immunity applies to “any claim for loss that has a causal relationship with

the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution, . . . dispensing, prescribing, [or] administration,. . . or use of such countermeasure.” 42 U.S.C. § 247d–6d(a)(2)(B), Plaintiff’s claims fall within this definition as they were “caused by” “ar[ose] out of, relate[d] to, or resulted from” the administration or use of the Moderna COVID-19 vaccine.

It should also be noted that other jurisdictions have applied PREP Act immunity in other types of tort cases involving administration of a COVID-19 vaccine. In *Storment v. Walgreen, Co.*, 1:21-CV-00898 MIS/CG, 2022 WL 2966607 (D.N.M. July 27, 2022),¹⁸ the District Court for the District of New Mexico found PREP Act immunity applied to the plaintiff’s premises liability claim and dismissed the matter with prejudice. *Id.* at *3. In that case, after receiving a COVID-19 vaccine, because there were no available chairs in the Walgreens store, Plaintiff Storment walked to her car to wait out the recommended 15-minute recovery period after receiving the vaccine. *Id.* at *1. Prior to reaching her car Plaintiff Storment became dizzy in the Walgreens parking lot, subsequently fell and injured her elbow. *Id.* After analyzing the same PREP Act immunity provisions, the *Storment* court concluded in part “[t]his chain of events is unfortunate and certainly deserving of a remedy, but it cannot be divorced from the administration of a covered countermeasure—the COVID-19 vaccine [plaintiff] received.” *Id.* at *3. The Court further determined that “Plaintiff’s remedy for her injuries following her COVID-19 vaccination is through the Countermeasures Injury Compensation Program (“CICP”).” *Id.* at *2.

¹⁸ Attached as Ex. I

Here, as in *Storment*, the circumstances of Plaintiff's claims are unfortunate. Nevertheless, her remedy likewise lies in the Countermeasures Injury Compensation Program rather than the instant suit.

iv. Plaintiff's Claims Arose During the Effective Period of the HHS Secretary's Declaration

PREP Act immunity for administration by an individual of a covered countermeasure applies only if the countermeasure was administered or used during the effective period of the declaration that was issued by the HHS Secretary with respect to the covered countermeasure. 42 U.S.C. § 247d-6d (a)(3)(A). “[I]f the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration . . . recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that [PREP Act immunity] is in effect with respect to the activities so recommended.” *Id.* at ¶ (b)(1).

On January 31, 2020, the HHS Secretary declared that as of January 27, 2020, a public health emergency existed because of COVID-19. That declaration has remained in effect through the present. On March 17, 2020, the HHS Secretary issued a declaration under the PREP Act “to provide liability immunity for activities related to medical countermeasures against COVID-19.” *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 FR 15198, 15199. The Declaration provides immunity for covered persons for the administration of covered countermeasures,

including “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . .” *Id.* at 15202.

Under the HHS Secretary’s Declaration, covered persons include “qualified persons” who are “authorized to prescribe, dispense, and administer COVID-19 vaccines . . .” *Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 7872, 7873.¹⁹ That includes State-licensed pharmacists, supervised pharmacy interns, and qualified pharmacy technicians. *Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 86 FR 41977, 41978. “[P]harmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B).” (Ex. D - PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, p. 2). Moreover, the PREP Act establishes “a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary . . ., of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.” 42 U.S.C. § 247d-6d(a)(1)(6).

In the present case, Plaintiff alleges in her Petition that on September 20, 2021, she received the Moderna COVID-19 vaccine from a Walgreens employee without her knowledge or consent. Accordingly, Plaintiff’s Claims Arose During the Effective Period of the HHS Secretary’s Declaration

¹⁹ As shown above, a pharmacist’s status as a “qualified person” extends to the pharmacy that employs them. (Ex. D - PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, p. 2)

C. Plaintiff has failed to Allege Willful Misconduct

PREP Act immunity requires Plaintiff to plead a federal cause of action for willful misconduct.

[T]he sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of Title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

42 U.S.C.A. § 247d-6d(d)(1). The PREP Act further provides that:

[n]o State . . . may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that ... (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the ... use, ... dispensing, or administration by qualified persons of the covered countermeasure.

42 U.S.C. § 247d-6d(b)(8). Finally, the PREP Act requires particular pleading for willful misconduct, specifically stating that a complaint must allege

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

42 U.S.C.A. § 247d-6d(e)(3). 30.

Additionally, even where a plaintiff makes sufficient allegations of death or serious physical injury proximately caused by willful misconduct, the PREP Act grants exclusive jurisdiction over such a claim to the District Court for the District of Columbia. *See* 42 U.S.C. § 247d6d(d)-(e).

In determining whether a federal law preempts a state law cause of action, the determinative inquiry is “Congress’ intent in enacting the federal statute at issue.” *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983). Whereas here, a federal law contains an express preemption clause, the focus is on the plain wording of the clause, “which necessarily contains the best evidence of Congress’ preemptive intent.” *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 593 (2011); quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

In this case, Plaintiff asserts state law only causes of action for negligence and vicarious liability against Walgreens. These causes of action are expressly preempted by the plain language of the PREP Act. *See* 42 U.S.C. § 247d-6d(d)(1). Furthermore, the Petition is devoid of any mention of a federal cause of action or particularized allegations of willful misconduct by Walgreens. Plaintiff’s Petition also offers no facts indicating the injection caused her death or serious physical injury.

Plaintiff has fallen short of the heightened pleading requirements for willful misconduct as required by the PREP Act, which requires particularized claims of “each act or omission” of a defendant, as well as the basic pleading standards required by *Twombly* and *Iqbal*. *See* 42 U.S.C. § 247d-6d(d)(1). Accordingly, all causes of action asserted against Walgreens should be dismissed.

D. Plaintiffs Have Failed To Exhaust Administrative Remedies

Plaintiff’s claims must also be dismissed due to a failure to exhaust administrative remedies. The PREP Act requires a plaintiff to exhaust all remedies available in the “Covered Countermeasure Process Fund” before pursuing litigation.

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d-6d(d) of this title against a covered person (as such term is defined in section 247d-6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d-6d(d) of this title.

42 U.S.C. § 247d-6e(d)(1).

Here, Plaintiff claims negligence by a covered person in the administration or use of a covered countermeasure. Plaintiff has not exhausted the remedies available under the Covered Countermeasure Process Fund. Further, Plaintiff has not established that the Covered Countermeasure Process Fund lacks funding or that the Secretary has failed to make a final determination on a request for benefits made by Plaintiff within 240 days after such request.

42 U.S.C. § 247d-6e(d)(1).

IV. CONCLUSION

Walgreens and its employee, Austin Crandall, were “covered persons” administering a “covered countermeasure” during the COVID-19 crisis. Accordingly, Plaintiff’s state law claims are expressly preempted by the PREP Act and there has been no showing of willful misconduct.

WHEREFORE premises considered, Walgreens respectfully prays the Court enter an order dismissing all claims brought against it in the underlying Petition by Plaintiff Rebecca Cowen, and for such other relief the Court deems just and equitable.

Respectfully submitted,

HOLDEN LITIGATION, *Holden P.C.*



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CERTIFICATE OF SERVICE

I hereby certify that on the 11 day of August, 2022, I electronically transmitted the attached document to the Clerk of Court using the ECF System for filing. Based on the records currently on file, the Clerk of Court will transmit a Notice of Electronic Filing to all counsel of record in this action.

s/Caleb McKee

Caleb McKee

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